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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,784	05/22/2006	Roger Le Comte	284302US6PCT	3618

22850 7590 05/11/2010
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER

HANDY, DWAYNE K

ART UNIT	PAPER NUMBER
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1797

NOTIFICATION DATE	DELIVERY MODE
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05/11/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/564,784	COMTE, ROGER LE	
	Examiner	Art Unit	
	DWAYNE K. HANDY	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 January 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 19-24 and 28-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Fischer et al. (5,646,046). This rejection was applied in the previous Office Action (mailed 10/01/09). It remains in effect. Please see Response to Arguments below.

3. Claims 19-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Burns et al. (US 2003/0054542). This rejection was applied in the previous Office Action (mailed 10/01/09). It remains in effect. Please see Response to Arguments below.

Response to Arguments

4. Applicant's arguments filed 01/04/10 have been fully considered but they are not persuasive. Applicant has argued that the instrument of Fischer is not a quality control device (Page 8 of Arguments):

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"Fischer concerns a method and instrument for automatically performing analysis relating to thrombosis and hemostasis by spectrophotometry. The instrument of Fischer is **not a quality control device for control bloods**. Instead, the instrument of Fischer conducts different assays to measure hemostasis or thrombosis parameters of samples in test wells using particular reagents. Any disclosure of means for refrigeration, means for heating, means for stirring, and means for sampling disclosed in Fischer is **limited to samples and/or reagents, not control bloods**. The only disclosure related to quality control in Fischer is related to monitoring the performance of the method and evaluating the validity of the reported data for the sample. Such disclosure is not relevant to the instantly claimed device. Finally, being directed to a different kind of testing, the instrument of Fischer naturally does not comprise means for sampling bloods or re-suspending of the cells."

The Examiner notes that the highlighted passages are intended use arguments. The Examiner reminds Applicant that the claims are drawn to a device, not a method. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Applicant has also argued that Fischer does not comprise means for sampling bloods or resuspending of the cells. The Examiner respectfully disagrees and notes that Applicant's sampling means as disclosed in the Specification is simply a needle. This is the same device taught by Fischer. See column 9 of Fischer and Paragraph 3 of the Previous Office Action.

5. Applicant has also argued that the device of Burns is not a quality control device (Pages 8-9 of Arguments):

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“Again though, the device in Burns does not teach the presently claimed quality control device **for control bloods incorporated into a blood analyzer**. The Burns device is designed for providing specimens to reaction receptacles within an automated analyzer to conduct nucleic acid-based assays. The device **works on serum and not on whole blood**. The means disclosed therein are **for samples and/or reagents and not control bloods**. Accordingly, the Burns device teaches nothing about control bloods. Moreover, no means for re-suspension of the cells is disclosed by Burns. Further, there is no means for storing control bloods inside the analyzer.”

The Examiner again notes that the highlighted passages are intended use arguments. The Examiner reminds Applicant that the claims are drawn to a device, not a method. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Applicant has also argued that Burns does not comprise means for storing bloods or means for resuspending the cells. The Examiner respectfully disagrees and notes that Applicant's resuspension means as disclosed in the Specification is a vortex stirrer, rocker or inverter (Paragraph 0065). Burns teaches an orbital shaker in Paragraph 0326. The Examiner submits this is a vortex stirrer. Applicant has argued that Burns does not teach means for storing blood by refrigeration. The Examiner respectfully disagrees and submits Burns recites multiple means for storage including the cooling bay (900) and a Peltier device (Paragraphs 0241-0258).

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DWAYNE K. HANDY whose telephone number is (571)272-1259. The examiner can normally be reached on M-F 11:00-7:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Dwayne K Handy/
Examiner, Art Unit 1797

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797

April 24, 2010